ICS AirCal

AirCal

Reference Manual

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Technical support
Please contact your supplier.

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1 Introduction

Congratulations! You are now the owner of a new ICS AirCal irrigator.

The ICS AirCal was developed based on the 30 years of knowledge and being the market leader in caloric irrigators. We maintained all the accuracy and functionality of the ICS NCA-200 while adding functionality that will improve workflow. In addition, the ICS AirCal is designed to be much quieter, smaller, and lighter in weight.

The ICS AirCal irrigator is a convenient and accurate air caloric stimulator to be used for evoking nystagmus during VNG/ENG examinations. The system provides thermal stimulation through the use of a carefully controlled flow of air. The air temperature is adjustable from 12°C to 50°C. The system provides for presetting two temperatures -- one for the warm and one for the cool caloric stimulation. Precise temperature control is maintained through the use of a thermistor located close to the point of airflow delivery. The innovative design of the otoscopic delivery head allows observation of the point of stimulation, assuring valid and repeatable responses.

To assist you in getting the most out of the ICS AirCal system, we have included this user manual. We hope you find it easy to use and that your use of the incorporated tips and information results in improved data collection accuracy as it relates to your assessment of vestibular-related disorders.

1.1 Intended Use

An air caloric stimulator is a device that delivers a stream of air to the ear canal at controlled rates of airflow and temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semicircular canals produces involuntary eye movements that are measured and recorded by a nystagmograph.

> ***Note*** • *The ICS AirCal System is intended to be used only by qualified medical personnel.*

1.2 Intended User

This manual describes the use of the device. Readers are assumed to have prior knowledge of the medical and scientific facts underlying the procedure. For this reason, the examination methods are mentioned only to the degree that is necessary for a correct, safe application of the ICS AirCal system.

1.3 About this manual

This is your guide to using the basic functions required for performing a caloric irrigation using the ICS AirCal. This includes key functionality such as temperature settings and selection, setting of duration timer and airflow rate, and use of irrigation delivery handle and foot switch.

1.4 Training

It is recommended that you make yourself familiar with the features provided by the ICS AirCal device before testing a patient.

1.4.1 Safety

This manual contains information, cautions, and warnings which must be followed to ensure the safe performance of the ICS AirCal system.

Caution • *Local government rules and regulations, if applicable, should be followed at all times.*

Safety information is stated where it is relevant, and general safety aspects are described inICS AirCal System Safety ► 29.

1.5 Typographical conventions

The use of Warning, Caution and Note

For safety reasons and appropriate use of the device and/or software, the manual contains **Warnings**, **Precautions** and **Notes**. These headings are used as follows:

Warning • *Indicates that there is risk of death or serious injury to the user or patient.*

Caution • *Indicates that there is a risk of injury to the user or patient or risk of damage to data or the device.*

Note • *Indicates that you should take special notice.*

2 Comparing Air Irrigation to Water Irrigation

Several studies have shown that both air and water irrigations can create comparable caloric responses. However, in order to obtain a comparable caloric response the air irrigator must be able to heat and cool the air, and the air stream must be able to be delivered directly to the tympanic membrane (i.e., the eardrum). The ICS AirCal meets both of these criteria. The following are the recommended settings for Air Irrigation:

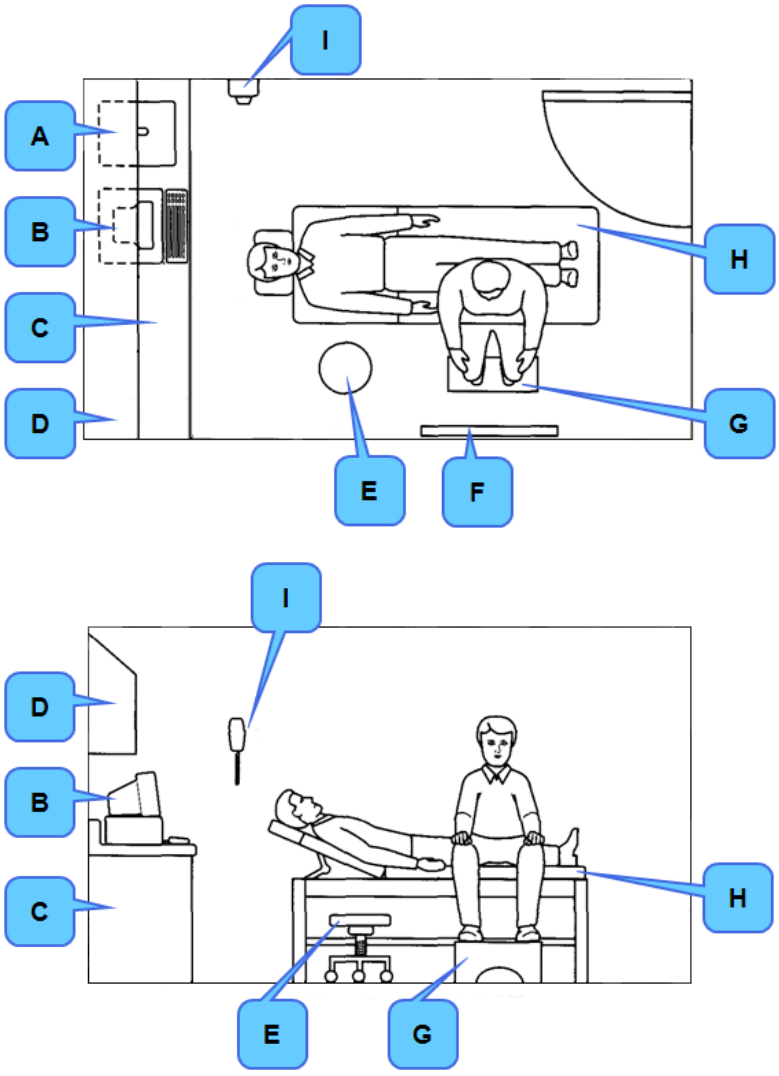
- Air temperatures: 50°C warm, 24°C cool
- Airflow rate: 8 liters per minute
- Irrigation Duration Time: 60 seconds

Literature supporting the above statement is below:

- Barin, K. (2008). Background and Technique of Caloric Testing. In Balance Function Assessment and Management. 1st ed. San Diego: Plural Publishing: 197-228.
- Barin, K. (2008). Interpretation and Usefulness of Caloric Testing. In Balance Function Assessment and Management. 1st ed. San Diego: Plural Publishing: 229-252.
- British Society of Audiology (1999) Recommended Procedure: Caloric Testing. British Journal of Audiology 33: 179-184.
- Ford, CR & Stockwell, CW (1978) Reliabilities of air and water caloric responses. Archives of Otolaryngology 104: 380-382.
- Zapala, D & Shaughnessy K Water vs. Air - Are they equivalent caloric stimuli? - Mayo Clinic Jacksonville, FL
- Zapala, DA; Olsholt KF & Lundy LB (2008) The comparison of water and air caloric response sand their ability to distinguish between patients with normal and impaired ears. Ear & Hearing 29(4): 585-600.

3 Getting started

3.1 Room Setup



A. Sink
B. VNG/ENG Equipment
C. Counter
D. Cabinets over counter
E. Examiner's stool
F. Light bar
G. Footstool
H. Examining table
I. Telephone

The ICS AirCal is designed to be used at any convenient level such as on a table, or cart. The ICS AirCal can be stacked with the Chartr 200 VNG/ENG hardware. It is best if the ICS AirCal is on top in order to refill the water as needed. Make sure the delivery head can reach the patient's ear. Make sure the stool can be adjusted to a height that will allow you to view the tympanic membrane (i.e., the eardrum) while performing irrigation.

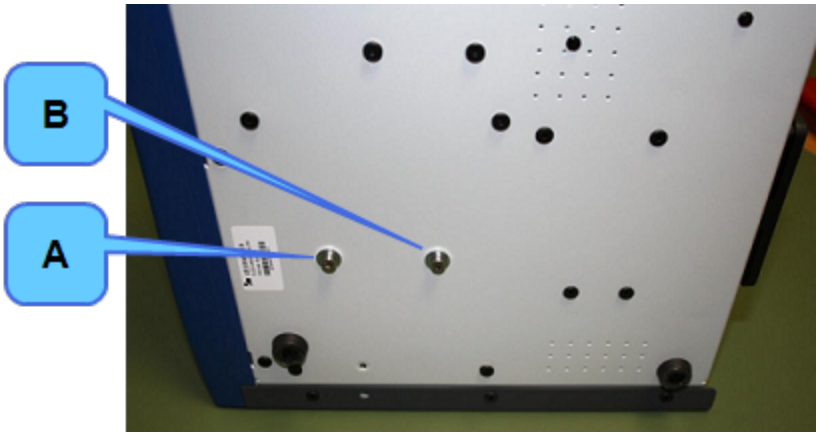
Note *• The ICS AirCal can be ordered in 2 different cable lengths 3 meter/10 feet (standard) and 4 meter/13 feet (extended). The decision on which to order should occur prior to purchase.*

3.2 Installation and setup

3.2.1 Removing the transportation screws

To prevent possible damage during shipping, the air pump housing is secured with transportation screws. These screws must be removed to allow the housing to move and thereby reduce the amount of noise the air pump produces. It is important to keep the transportation screws to secure the housing in the event the device needs to be shipped.

1. Remove transportation screws (A) and (B).
2. Store them with your Syringe Kit, Funnel and Allen Key.

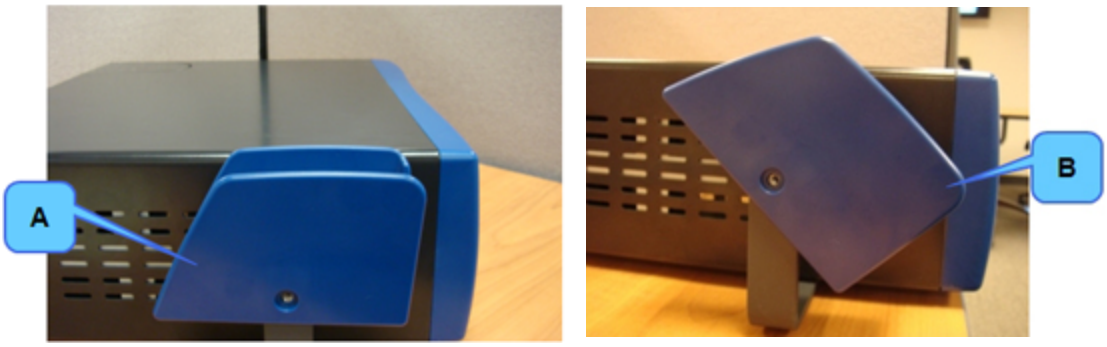


3.2.2 Installing the Delivery Head Cradle

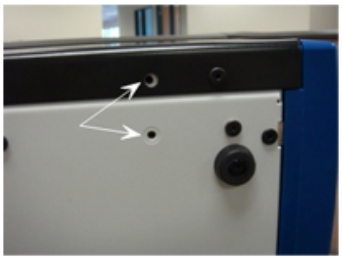
Caution *• Install the cradle prior to filling the water reservoir. Installation requires that the ICS AirCal is tilted more than 20°. If the water reservoir has water in it, tilting the device could introduce air into the system. There is little chance of damage to the system but, priming of the water reservoir would be required to make the system operate properly and not overheat.*

Before installing the cradle for the delivery head determine how it should be mounted:

- The cradle can be mounted on the left or right side of the unit.
- For units placed away from the edge of the table, it is recommended that the cradle is mounted in the horizontal position (A).
  For units placed at the edge of the table, it is recommended that the cradle is mounted at an angle (B).



1. Locate the bag shipped with the cradle that contains 3 screws and an Allen key.
2. With the side chosen to hold the cradle facing the ceiling and the bottom of the unit facing you, lay the ICS AirCal on its side.
3. Locate the bracket mounting holes.



4. Attach the bracket to the unit using the Allen key to tighten the screws.
5. Hold the cradle with the end that holds the bottom of the delivery head facing the front of the unit. Slide the cradle onto the bracket in the horizontal position.

6. For units placed at the edge of the table, tilt the bracket forward until it stops.
7. Ensure the mounting hole on the bracket aligns with the mounting hole of the cradle. Attach the cradle to the bracket using the Allen key to tighten the screw.
8. Store the Allen key with the syringe kit. You will need it when filling the water reservoir.

3.2.3 Understanding the ICS AirCal Back Panel

***Note** • The USB port allows for firmware upgrades. Refer to* *Firmware procedures ► 41*

3.2.3.1 Connecting the Foot Switch

The foot switch comes standard with the ICS AirCal. Connect the foot switch to the back of the irrigator. If the ICS AirCal is connected to an ICS VNG/ENG system and you want to use the foot switch to start tests other than the caloric test, you need to have the irrigator on in order to use the foot switch.

3.2.3.2 Connecting to an ICS VNG/ENG system

The ICS AirCal can be connected to an ICS VNG/ENG system. Connect the irrigator cable to the back of the irrigator and to the ICS VNG/ENG system.

Connecting the 2 devices together gives additional functionality. See Activation Trigger Operation ► 24 for more information.

3.2.3.3 Connecting the Mains power cable

The ICS AirCal should be connected to an electrical wall outlet by attaching the power cable to the ICS AirCal irrigator and plugging the cable into the electrical wall outlet.

A. Connector for power cable

3.2.3.4 Filling and priming procedure

The ICS AirCal uses water to cool the air. It is required that the water reservoir be filled prior to use of the device.

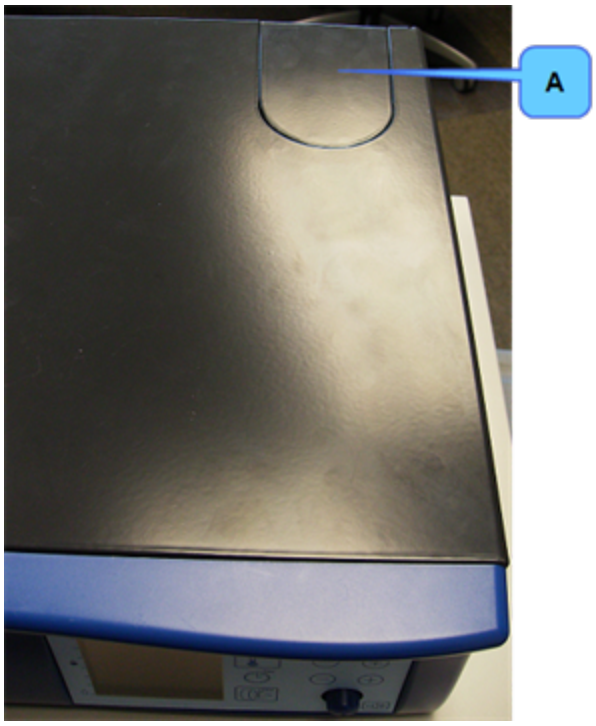
Warning • *To prevent electrical shock, the ICS AirCal irrigator must be turned off and disconnected from the electrical wall outlet when filling or refilling the water reservoir.*

Caution • *Use this procedure if: 1) the ICS AirCal was just received from shipping dry. It needs to be filled and primed, 2) If the water level in the display has gone to zero because user never refilled it when orange bar was present. 3) If the ICS AirCal was tilted at more than 20° with the water pump running.If none of these criteria were met and the water level display is showing an orange bar and needing refill, please follow the instructions in* *Refill Procedure: ► 22 .*

Caution • ***Only*** *use distilled water. Using common water from the tap will result in mineral deposits and will harm the ICS AirCal.*

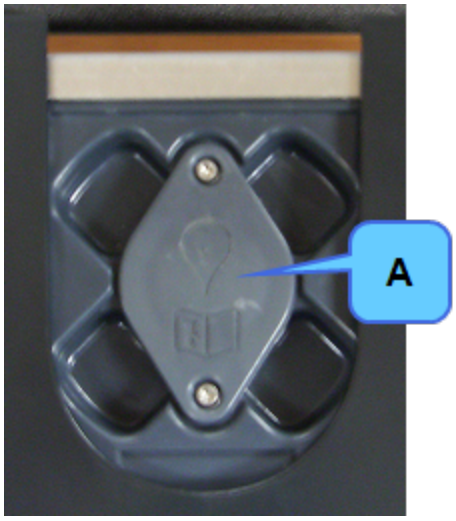
Filling

1. Turn off the ICS AirCal irrigator and unplug from the electrical wall outlet.
2. Wipe off any dust on the top of the case.
3. Facing the front panel, locate the small cover at the back right side. Using the Allen key (supplied with the cradle) unscrew the reservoir cover and remove.



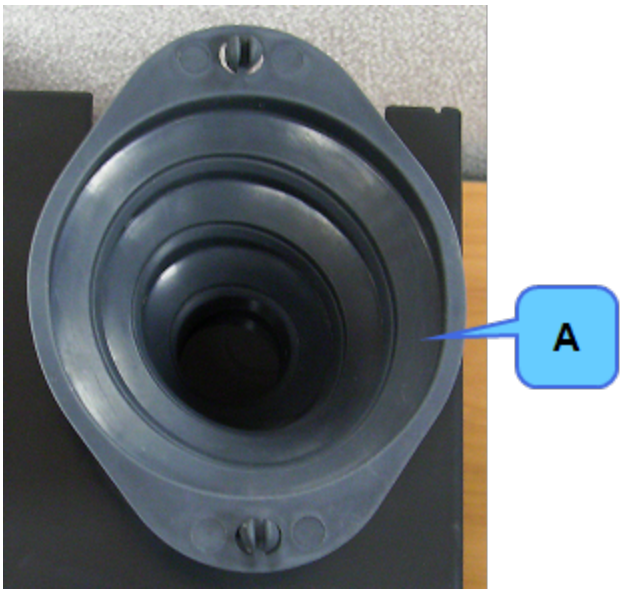
A. Reservoir cover

4. Using the Allen key unscrew the internal cover and remove.



A. Internal cover

5. Expand the funnel supplied with the ICS AirCal irrigator and place in the refill hole of the reservoir.



A. Funnel

6. Pour water into the funnel to fill the reservoir.
7. Monitor the water level closely. Fill to the bottom of the lip. Do NOT overfill the reservoir.
8. Remove the funnel.
9. Wipe up any excess water that might have spilled into the small indentions where the internal cover is placed.
10. Replace the internal cover.

Priming

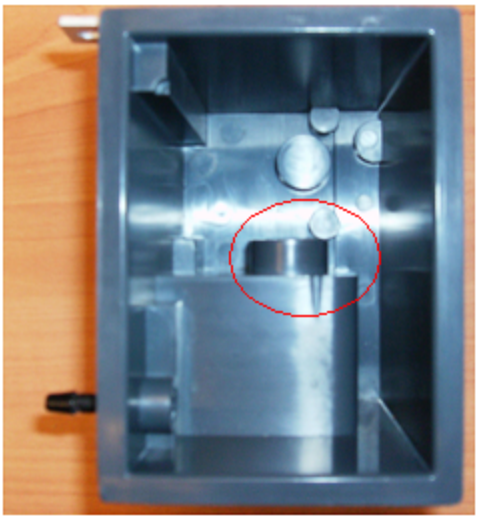
1. Plug in the irrigator into the electrical wall outlet and turn on.
2. Turn off the airflow.
3. Locate the priming switch on the back panel .
4. Press the priming switch to turn on and hold 5 seconds.
5. Release the priming switch to turn off and wait 5 seconds.
6. Repeat steps 4 and 5 for a total of 10 times on and 10 times off.
7. Press the cool button . Decrease the temperature to 12°C.
8. If the temperature reaches the set temperature, then the irrigator is primed. Continue to step 10.
9. If the temperature does not reach 12°C in approximately 3 minutes or, if the over temperature alarm sounds, skip to the procedure Priming with bent tube ► 16.
10. Turn off the irrigator and unplug from the electrical wall outlet.
11. Remove the internal cover.
12. Check if the water reservoir is full. If not, place the funnel in the refill hole of the reservoir and add additional water.
13. Remove the funnel and replace the internal cover. Tighten the screws to secure.

14. Replace the external cover and tighten screws to secure.
15. Plug in the irrigator into the electrical wall outlet and turn on.

> ***Note*** • *The default airflow rate for caloric irrigation is 8 liters per minute. Shipping may cause the airflow knob to move. You may have to reset the airflow.*

Priming with bent tube

1. Take the syringe with bent tube and remove enough water from the reservoir to fill the syringe.
2. Put the end of the bent tube into the pump inlet hole. The tube will be facing toward the front of the irrigator.



3. While pressing the priming switch, inject the water into the inlet.
4. Release the priming switch.
5. Press the priming switch to turn on and hold 5 seconds.
6. Release the priming switch to turn off and wait 5 seconds.
7. Repeat steps 5 and 6 for a total of 10 times on and 10 times off.
8. Press the cool button . Decrease the temperature to 12°C.
9. If the temperature reaches the set temperature, then the irrigator is primed. Continue to step 11.
10. If the temperature does not reach 12°C in approximately 3 minutes or,repeat steps 1 through 9.
11. Turn off the irrigator and unplug from the electrical wall outlet.
12. Check if the water reservoir is full. If not, place the funnel in the refill hole of the reservoir and add additional water.
13. Remove the funnel and replace the internal cover. Tighten the screws to secure.
14. Replace the external cover and tighten screws to secure.
15. Plug in the irrigator into the electrical wall outlet and turn on.

> ***Caution*** *• Due to the possibility of freezing during shipment, water must be drained from the reservoir before shipping the ICS AirCal. See Troubleshooting ► 39 for draining instructions.*

3.2.4 Cleaning and maintenance

3.2.4.1 ICS AirCal device

Keep the instrument clean and as free of dust as possible. To clean the outside case or delivery head, use a soft slightly damp cloth with a small amount of mild detergent.

3.2.4.2 Lens on the Delivery Head

The Lens can be cleaned with a cleaning cloth like the Otometrics optical cleaning cloth (part # 7590527).

3.2.4.3 Speculum (outer)

The speculum is disposable and single-use only. It is not recommended that they be cleaned. Additional specula (part # 8-62-44100 - Qty 25) can be obtained from Otometrics or your local representative.

4 ICS AirCal Front Panel

This section describes all operational controls located on the front panel of the ICS AirCal.

4.1 ICS AirCal device on/off

This is a push on/push off switch located on the bottom left of the front panel that applies power to the ICS AirCal. On is indicated by the illumination of a green LED and the digital display. When the ICS AirCal is first turned on it is in operation mode.

4.2 Standby/Operation Mode

When the ICS AirCal is turned on the default is airflow on. Pressing the airflow button will switch the ICS AirCal between standby mode and operation mode. In standby mode (airflow off), the irrigator is on but the airflow, water and air pump, fan, warming and cooling mechanisms are off. Standby mode is recommended when the ICS AirCal is connected to an ICS VNG/ENG and the foot switch is used for starting other tests (e.g., Dix Hallpike) in the Chartr software. Turn off the airflow when the device is not in use.

4.3 Temperature

4.3.1 Recommended/Default Temperature

The default temperatures are 24°C for cool and 50°C for warm. These temperatures are recommended based on literature that states using these temperatures will create a comparable caloric response as water irrigation. See Chapter Comparing Air Irrigation to Water Irrigation ► 7 for more information.

4.3.2 Setting a new temperature

4.3.2.1 Temporary Adjustment

To adjust the temperature for a single patient use, press the buttons. The - decreases the temperature, the + increases the temperature. Press button quickly if small increments are needed or press and hold to change more rapidly. The range for the cool temperature is 12°C to 37°C. The range for the warm temperature is 37°C to 50°C. The temperatures are adjustable in 1/10 of a degree increments. To change the warm or cool temperature stored default value, see Changing the Stored Default Values ► 21.

4.3.3 Switching between cool and warm temperature

The warm or cool temperature buttons allow the operator to select the stimulus desired. If the ICS AirCal is connected to an ICS VNG/ENG system, selecting the caloric protocol (e.g., Left Warm) will automatically select the temperature on the irrigator. Therefore, no manual selection is needed. However, the default startup temperature of the ICS AirCal should match the temperature of the first caloric protocol in your list (e.g. if you start with Left Cool - default the ICS AirCal to start with Cool). The startup temperature (cool or warm) can be stored. The default is cool. See Section Changing the Stored Default Values ► 21.

Temperature selection will be indicated on the display panel. If the ICS AirCal is in operation mode only the temperature currently selected will display. The digital display shows the actual and set temperatures. Once a temperature has been selected, the display will flash until it reaches +/- 0.3 degrees from the set or default temperature. Time to reach the temperature is < 60 seconds. If the ICS AirCal is in standby mode both the warm and cool set temperatures will display, the actual temperature will not display.

4.4 Duration Timer

4.4.1 Recommended/Default Duration Timer

The default duration for caloric irrigation is 60 seconds. This duration is recommended based on literature that states this duration will create a comparable caloric response as water irrigation. See Chapter Comparing Air Irrigation to Water Irrigation ► 7 for more information.

4.4.2 Setting a new Duration Time

To adjust the duration time, press the buttons. The - decreases the time, the + increases the time. Press button quickly if small increments are needed or press and hold to change more rapidly. The range for the time is 1 to 99 seconds. To change the duration time stored default value, see Section Changing the Stored Default Values ► 21.

Duration Time selection will be indicated on the display panel. If the ICS AirCal is in operation mode, the digital display shows the set time. Once an irrigation is started by using the foot switch or activation trigger on the delivery head, the actual timer will count down to 0. A beep will sound when the timer reaches 0 to alert the tester to stop irrigation. If the ICS AirCal is in standby mode only the set time will display.

4.5 Airflow Rate

4.5.1 Recommended/Default Airflow Rate

The default airflow rate for caloric irrigation is 8 liters per minute. This duration is recommended based on literature that states this duration will create a comparable caloric response as water irrigation. See Comparing Air Irrigation to Water Irrigation ► 7 for more information.

4.5.2 Setting a new Airflow Rate

Turn the knob to the right of the airflow button to adjust the flow rate. Turn the knob counterclockwise to increase the airflow and clockwise to decrease the airflow. The range for the airflow rate is 4 to 10 liters per minute. The airflow rate is set based on the knob position.

The flow rate selection (actual only) will be indicated on the display panel. If the ICS AirCal is in operation mode, the digital display shows the actual flow rate. If the ICS AirCal is in standby mode the display will be off.

4.6 Beep Volume

A beep will sound when the timer reaches 0 to alert the tester to stop irrigation. A 2000 Hz beep is presented.

4.6.1 Default Beep setting

The default Beep is set to level 2.

4.6.2 Setting a new beep volume

To adjust the beep volume, press and hold the beep button until a beep is sounded that you want as the default. There are 4 levels for the beep volume. To change the beep volume stored default value, see Changing the Stored Default Values ► 21.

4.7 Changing the Stored Default Values

Change all settings to the desired setting. Decide what temperature for the ICS AirCal to start up in. Press and hold either the warm or cool temperature button for 3 seconds to set all default settings (warm and cool temperatures, startup temperature, duration timer and beep volume). A 1 second beep will be sounded to confirm that the default settings have been stored. Remember, the default startup temperature of the ICS AirCal should match the temperature of the first caloric protocol in your list (e.g. if you start with Left Cool - default the AirCal to start with Cool).

4.8 Water level display

The water level of the water in the reservoir is displayed. The symbol indicates that the water reservoir is full and a blue bar will display. The symbol indicates that the water reservoir is half full a blue bar will display. Between half full and empty the bar will change from blue to orange this indicates that the water reservoir needs to be refilled. And symbol indicates that the water reservoir is empty.

4.8.1 Refill Procedure:

> ***Caution*** • *Do NOT use this refill procedure if: 1) the ICS AirCal was just received from shippingdry. It needs to be filled and primed, 2) If the water level in the display has gone to zero because user never refilled it when orange bar was present. 3) If the ICS AirCal was tilted at more than 20° with the water pump running. If one of these criteria were met please refer to Getting started ► 9 and follow the Filling and priming procedure ► 13.*

> ***Caution*** • ***Only*** *use distilled water. Using common water from the tap will result in mineral deposits and will harm the ICS AirCal.*

1. Turn off ICS AirCal and disconnect from the electrical wall outlet.
2. Wipe off any dust on the top of the ICS AirCal prior to opening the case to refill the reservoir.
3. Face the ICS AirCal front panel. On the back right side is a small cover. Using the Allen key (supplied with the irrigator cradle) unscrew the cover and remove.
4. Using the Allen key unscrew the internal cover and remove.
5. Expand the funnel supplied with the ICS AirCal.
6. Place the funnel in the refill hole of the reservoir.
7. Pour water into the funnel to fill the reservoir.
8. Monitor the water level closely. Fill to the bottom of the lip. Do NOT overfill the reservoir.
9. If water was spilled into the small indentions where the internal cover is placed. Wipe up this excess water before replacing the internal cover.
10. Replace the internal cover and tighten the screws.
11. Replace the external cover and tighten the screws.
12. Plug in the ICS AirCal to the electrical wall outlet and turn on ICS AirCal.

> ***Caution*** • *Due to the possibility of freezing during shipment, water must be drained from the reservoir before shipping the ICS AirCal. See Troubleshooting ► 39 for water removal instructions..*

5 ICS AirCal Delivery Head & Foot Switch

5.1 Delivery Head

The delivery head can be held in any way that is comfortable for the tester. Flow time activation is accomplished by an activation trigger located on the delivery head. The otoscope light can be turned on and off using the button located on the back of the handle below the lens.

> ***Note*** • *Turn light off when not in use.*

> ***Note*** • *Caution symbol indicates that the inner speculum should never be placed in the ear without an Outer Disposable Speculum attached to it.*

A. Inner Speculum
B. Flow Time Activation Trigger
C. Full View Otoscope Lens
D. Light On/Off Button

5.1.1 Speculum

> ***Warning*** • *Never place the inner speculum directly into the patient's ear.*

An outer disposable speculum should always be placed on the delivery head prior to performing an irrigation on a patient. The outer disposable speculum is intended to be single-use only.

5.1.2 Lens

The Lens can be cleaned with a cleaning cloth like the Otometrics optical cleaning cloth (part # 7590527). If the lens is mishandled and broken a new lens can be purchased. Slide the broken lens out and slide the new lens into place. See Section 8.1 for an Accessories list.

5.1.3 Light on/off button

The light should be left on during irrigation in order to view the tympanic membrane (i.e., the eardrum) to ensure that the airflow is being directed properly.The light defaults to on when the ICS AirCal is in operation mode. The light will flash when the caloric test/irrigator is initiated by pressing the foot switch or the activation trigger on the delivery head to confirm initiation of the devices. If the ICS AirCal has not been used for 10 minutes the light will automatically shut off.

5.1.4 Activation Trigger Operation

If airflow is on and temperature is +/- 0.3 of the set value, pressing the activation trigger on the handle will start the countdown timer and flash the light in the delivery head (set temperature must be reached in order to start timer and for light to flash).

If the ICS AirCal is connected to an ICS VNG/ENG system:

In VNG, first depression also starts the tracing and successive depressions start the video recorder or center tracing depending on software configuration.

In ENG, first depression also starts the tracing and successive depressions centers the tracing.

If the computer is turned on but the Otometrics VNG/ENG software is not running, flow time may be activated by holding down the flow time activation trigger for 5 seconds. The functions of the flow time activation trigger operate in parallel with the foot switch on the delivery head.

Pressing the activation trigger on the handle more than once will NOT stop or restart the countdown timer.

If airflow is off, pressing the activation trigger on the handle will NOT start the countdown timer.

5.2 Foot Switch

5.2.1 Operation

A foot switch is used to activate the flow timer.

If an ICS VNG/ENG system is connected and a caloric test has been selected in the software, the first depression of the foot switch will initiate the duration timer and the recording of the trace in the software; subsequent depressions will center the tracing (ENG/VNG) or start the video recording (VNG only).

If the computer is turned on but the Otometrics VNG/ENG software is not running, flow time may be activated by holding down the foot switch for 5 seconds. The functions of the foot switch operate in parallel with the flow time activation trigger on the delivery head.

Pressing the foot switch more than once will NOT stop or restart the countdown timer.

If the ICS AirCal is in standby mode, pressing the foot switch will NOT start the countdown timer. In standby mode the foot switch can start any test in the ICS VNG/ENG software.

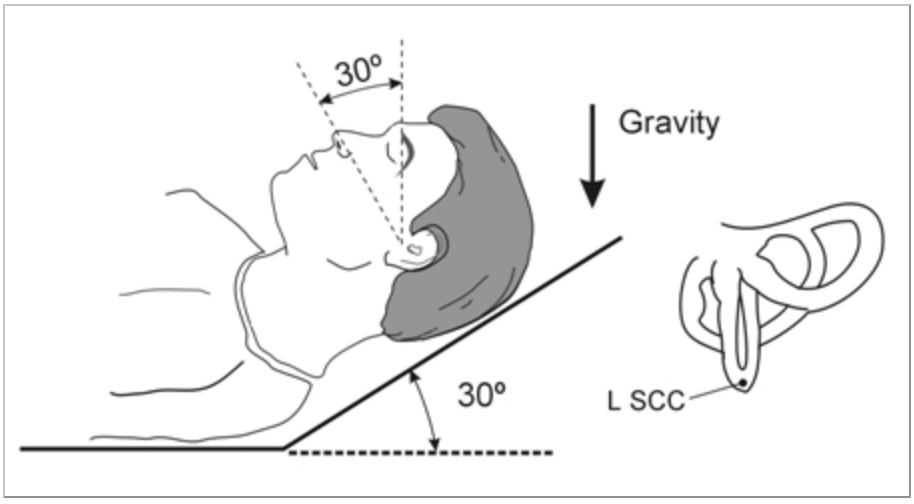
6 Performing a Caloric Irrigation

6.1 Preparation for testing

Turn the unit on by pressing the power switch at the bottom left of the front panel. The default temperature (cool is manufacturer default) will automatically be selected as indicated by the illumination of the green LED and the digital display. The actual temperature will flash until the set temperature is reached. It takes approximately 60 seconds for set temperature to be reached when the unit is first turned on. When the set temperature is reached (±0.3°C), the actual temperature display will stop flashing.

Using a regular otoscope or the delivery head with airflow turned off, examine the ear canal for the presence of cerumen and also to determine how best to direct the airstream. The ear canal should be essentially free of cerumen. If it is not, this must be removed prior to stimulating. Do not use water to remove cerumen as this will cause the temperatures in the ear canal to be cooler than desired due to left over water in the ear canal.

Verify that the patient is positioned properly, in the supine position with head flexed 30º.



6.2 Testing Procedure

Perform each of the four irrigations as follows:

1. Verify that a new speculum has been placed on the delivery head.
2. Instruct the patient to keep eyes open (VNG) or closed (ENG).
3. Close goggles for VNG. Have patient close their eyes for ENG.
4. Start collecting response and start irrigation.
5. Start tasking patient 20-30 seconds into irrigation.
6. When duration time is reached the ICS AirCal will present a beep, remove the delivery head from the patient's ear and continue tasking.
7. Right after the peak of the response, allow patient to fixate.
8. Collect eye movements until response subsides.
9. Dispose of the speculum and carefully place the delivery head in its cradle.

If the ICS AirCal is connected to an ICS VNG/ENG system, subsequent depressions of the flow time activation switch will center the tracing for VNG/ENG or start the video recording for VNG. (If installed, the foot switch will also serve to start and center tracings or start the video recording.)

7 ICS AirCal System Safety

This manual contains information, cautions, and warnings which must be followed to ensure the safe performance of the ICS AirCal system. Local government rules and regulations, if applicable, should be followed at all times.

When the ICS AirCal device is used in conjunction with a test device, make sure that all information, cautions, and warnings in the User Manual for the test device are followed. For safety specifics concerning test modules and test devices, see the specific manuals.

7.1 Symbols used

ICS Impulse System	
	Caution symbol: Refer to ICS AirCal Delivery Head & Foot Switch ► 23.
	Consult instructions for use.
	Follow instructions for use.
	Complies with Type BF requirements of IEC60601-1.
	This product is Classified by UL as to electrical shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601-1.
	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.
	Complies with Medical Devices Directive 93/42/EEC.
	Located on Front Panel. Power on/off switch
	Located on Back Panel. Port for Foot Switch
	Located on Back Panel. Port for ICS VNG/ENG system
	Located on Back Panel. Port for Computer (used for firmware upgrades and future development)
	Located on Back Panel. Priming Switch for Water Reservoir

7.2 Warning notes

GN Otometrics ICS products are not designed to be used in conjunction with any

devices not approved by GN Otometrics. Summation of combined unapproved parts could result in increased electrical leakage. All parts of the ICS AirCal Device are suitable for use within the patient environment.

1. For the sake of safety, and in order not to void the warranty, the ICS AirCal should only be serviced by authorized service personnel. In case of defects, please make a detailed description of the defect(s) and contact your supplier.
   Do not use a defective instrument.
2. Keep the unit away from liquids. Do not allow moisture inside the unit.
3. Do not use the instrument in the presence of flammable anesthetics (gases).Do not use the equipment in the presence of flammable anaesthetics (gases).
4. No parts may be eaten, burnt, or in any way used for purposes other than the applications defined in the Intended Use section of this manual.
5. The equipment can be disposed of as normal electronic waste according to local regulations.
6. For safety reasons, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
7. Never place the delivery head speculum into a patient's ear without first attaching the outer disposable speculum. The speculum should be carefully placed into the patient's ear. Avoid excessive force or deep insertion as it could result in injury.
8. The ICS AirCal is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ICS AirCal can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment.
9. Immediately discontinue use of the equipment if skin irritation or discomfort occurs.
10. Only distilled water should be used when filling or refilling the water reservoir. Using common water from the tap will result in mineral deposits and will harm the ICS AirCal.
11. The default settings are recommended in order to deliver a stimulus that will produce a response comparable to water irrigation. Prolonged duration beyond 60 seconds or alternative temperature settings may result in patient discomfort.
12. Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e.IEC 950 for data processing equipment and IEC 60601-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.
13. TheICS AirCal irrigator needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect medical electrical equipment. The ICS AirCal irrigator may be interfered with by other equipment with CISPR emission requirements.
14. The use of accessories and cables other than those specified in the Accessories list of this manual may result in increased emissions or decreased immunity of the ICS AirCal irrigator.

7.3 Manufacturer

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9 Hoerskaetten, DK-2630 Taastrup
Denmark
+45 45 75 55 55
+45 45 75 55 59
www.otometrics.com

7.3.1 Responsibility of the Manufacturer

The manufacturer is to be considered responsible for effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.

8 Technical Specifications

Temperature range:12° to 50°C

- Cool stimulus:12° to 37°C (Recommended setting: 24°C)
- Warm stimulus:37° to 50°C (Recommended setting: 50°C)

Temperature readout: Digital

Time to temperature: < 60 seconds

Temperature accuracy: ± 0.3°C

Time range: 1 to 99 seconds (Recommended setting: 60 seconds)

Flow rate range: 4 - 10 liters per minute (Recommended setting: 8 liters per minute)

Flow rate accuracy: ± 0.4 liters per minute

Air supply: Internally mounted compressor

Remote control capability: When integrated with Otometrics VNG/ENG systems

Time-out indication: Internally generated Audible Beep

Input power: 85 VAC - 265 VAC @ 50 or 60 Hz (Rating stated is the worst case operating input voltage range. The typical input voltage range is 100-240VAC.)

Maximum Current: 1.6 A

Safety: Primary temperature read-out. Separate over-temperature cut-off.

Stimulus timing activation: Activation trigger on delivery head or foot switch.

Size	
Width	13.5 inches (34.3 cm)
Depth	12 inches (30.5 cm)
Height	4 inches (10.2 cm)

Weight
17.5 lbs. (7.9 kg) (with empty reservoir)

Operating Environment	
Temperature	+15°C to +35°C (59°F to +95°F)
Rel. Humidity	<90%, 35°C non-condensing
Air Pressure	600 hPa to 1060 hPa
Operations at temperatures below -20°C (-4°F) or above +60° C (140°F) may cause permanent damage.	

Storing and Handling	
Temperature	-25°C to +60°C (-13°F to +140°F)
Rel. Humidity	<90%, 35°C non-condensing

Storing and Handling	
Air Pressure	500 hPa to 1060 hPa
Reservoir	If the ICS AirCal is going to be stored for an extended period of time without usage or shipped the reservoir should be empty.

Calibration
Calibration of this system is not required. Local government rules and regulations, if applicable, should be followed at all times. However, if the system is not performing as expected a re-calibration may be needed.

Standards	
Safety	Complies with IEC60601-1, UL2601-1, CAN/CSA-C22.2 NO 601.1-90, Class II, Type BF, IPXO
EMC	IEC 60601-1-2

8.1 Accessories

Item	Part number
Specula (Qty 25)	8-62-44100
Lens (Qty 1)	8-35-33300
Syringe Kit (includes funnel)	8-62-46300
Funnel	1-12-66100
Cradle for Delivery Head	8-62-46200
Manuals CD	8-49-91500
7-pin mini-DIN cable (Chartr 200, Hortmann Vestlab)	8-71-90400
9-pin-subminiature to 7-pin mini-DIN (Chartr XP)	8-71-90300
Foot switch	8-35-39700
Power cord, IEC power hospital grade	7630024
Power cord, standard, EU	8-71-240
Power cord, UK	8-71-80200

8.2 Guidance and manufacturer's declaration tables

Electromagnetic Emissions

The ICS AirCal device is intended for use in the electromagnetic environment specified below. The customer or user of the ICS AirCal device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - Guidance
Radio Frequency (RF) Emissions CISPR 11	Group 1	The ICS AirCal device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ICS AirCal device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity - All Equipment and Systems

The ICS AirCal system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
EFT IEC 61000-4-4	±2kV Mains	±2kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>9 % dip in U_T) for 5 seconds	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>9 % dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of ICS AirCal system requires continued operation during power mains interruptions, it is recommended that ICS AirCal system be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity - Equipment and Systems that are not LIFE SUPPORTING

The ICS AirCal system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
			Portable and mobile communications equipment should be separated from the ICS AirCal system by no less than the distances calculated/listed below:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	d = 1.2 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2, 5 GHz	3 V/m 80 MHz to 2.5 GHz	d =1.2 √P for 80 to 800 MHz d = 2.3 √P for 800 MHz to 2.5 GHz
			where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM]. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications - Equipment and Systems that are not LIFE SUPPORTING

The ICS AirCalsystem is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of ICS AirCal system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and ICS AirCal system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80 MHz d=	80 to 800 MHz d=	800MHz to 2.5GHz d=
0.01	0.12	0.12	0.23
0.10	0.37	0.37	0.73
1.00	1.17	1.17	2.3
10.00	3.69	3.69	7.3
100.00	11.67	11.67	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9 Troubleshooting

Problem	
ICS AirCal Overheating Warning sounds an audible continuous beep. Causes: 1. Water Reservoir is low/empty. 2. ICS AirCal has been tilted 20° or more while the pump was operating, there is a risk of that the pump took in air instead of water. 3. ICS AirCal is not functioning properly.	**Option 1**: Look at the Water Level Display. If the bar is orange, this means you need to refill the water in the ICS AirCal. Turn off the ICS AirCal. Follow the Filling and Priming procedure in Filling and priming procedure ► 13. Turn on unit and verify that it is working properly. **Option 2**: Look at the Water Level Display. If the bar is blue, then you should have sufficient water but it should be verified. Turn off the ICS AirCal. Follow the Filling and Priming procedure in Filling and priming procedure ► 13. However, visually see if there is water present in the reservoir. If there is no or very low water refill the water. Turn on unit and verify that it is working properly. Whether the units works or not, contact Otometrics technical support and report that the ICS AirCal is not performing as expected.

Problem	
Water Removal Procedure ***Caution*** *• If shipping the device, make sure to* *1) Drain the water from the reservoir to prevent the possibility of damage caused by freezing, and* *2) Secure the air pump housing with the transportation screws supplied with the device.*	1. Turn the ICS AirCal off and unplug the ICS AirCal from the electrical wall outlet. 2. Wipe off any dust on the top of the ICS AirCal prior to opening the case to refill the reservoir. 3. Face the Irrigator Front Panel. On the back right side is a small cover. Using the Allen key (supplied with the cradle) unscrew the cover and remove. 4. Using the Allen key unscrew the internal cover and remove. 5. Using the Syringe Kit provided, remove the water from the reservoir. 6. Plug the ICS AirCal into the electrical wall outlet and turn ICS AirCal on. 7. Turn off the airflow. 8. To prime the pump, locate the priming switch on the back panel . 9. Press the priming switch to turn on and hold 5 seconds. 10. Release the priming switch to turn off and wait 5 seconds. 11. Repeat steps 9 and 10 for a total of 10 times on and 10 times off. 12. Turn ICS AirCal off and unplug the ICS AirCal from the electrical wall outlet. 13. Remove any remaining water. 14. If water was spilled into the small indentions where the internal cover is placed. Wipe up this excess water before replacing the internal cover. 15. Replace the internal cover and tighten the screws. 16. Replace the external cover and tighten the screws.

10 Firmware procedures

To upgrade the ICS AirCal firmware, locate the AirCal Firmware upgrade CD and a computer on which the ICS AirCal device driver has been installed. To install the device driver, follow the instructions in Installing the device driver ► 42 before continuing.

10.1 Upgrading the firmware

1. Turn off the ICS AirCal system.
2. On the back panel, locate the firmware mode button (accessed through hole A) and the ICS AirCal USB port (B).

A. Access to firmware button **B.** USB Port

3. Connect the USB cable to the ICS AirCal USB port and to the USB port on the computer.
4. Turn on the computer and insert the ICS AirCal firmware upgrade CD.
5. Using a ballpoint pen, press and hold the firmware mode button while turning on the ICS AirCal. Hold for 3 seconds (the display will be blank).
6. Double-click on the *AirCalFirmwareUpdate.exe* file to run the update program.
7. Click **Update AirCal Firmware**.

***Note** • If the upgrade is not successful, click **Write Update Log To Text File**. Send this file to Otometrics customer support.*

10.2 Installing the device driver

This procedure installs the device driver on the computer that will be used to update the ICS AirCal firmware.

1. Turn on the computer.
2. Insert the ICS AirCal firmware upgrade CD.
3. On the CD, inside *AirCal Driver* folder, locate the *AirCalInstaller.exe* file.
4. Double-click on the file to run the installer program.

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